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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO.       |
|---|-------------|----------------------|-------------------------|------------------------|
| 10/566,776  | 10/02/2006  | Andrew V. Schally    | SHAL3.0-032PCT/US       | 7750                   |
| 47375   | 7590        | 07/23/2007           |                         |                        |
| OMRI M. BEHR<br>325 PIERSON AVENUE<br>EDISON, NJ 08837-3123 |             |                      | EXAMINER<br>HA, JULIE   |                        |
|   |             |                      | ART UNIT<br>1654        | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>07/23/2007 | DELIVERY MODE<br>PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/566,776

Applicant(s)

SCHALLY ET AL.

Examiner

Julie Ha

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, 16-20 and 22-28, drawn to a peptide, a pharmaceutically administrable composition for the suppression of levels of GH and a method of suppressing IGF-I or IGF-II levels in the tumor tissue of a patient having a cancer carrying receptors for IGF-I by administering a suppressively effective amount of a compound.

Group II, claim(s) 21, drawn to a method of the treatment of a patient having a cancer carrying receptors for GH-RH by administering an amount of a compound effective to block GH-RH receptors.

A national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) a product and a process specially adapted for the manufacture of said product; or
- (2) a product and a process of use of said product; or
- (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) a process and a apparatus specifically designed for carrying out said process; or
- (5) a product, a process specially adapted for the manufacture of the said product and an apparatus specifically designed for carrying out said process. 37 CFR 1.475.

Group I, having a first product and a first method for making said product fall within category (2). PCT Rule 13 does not provide for multiple compositions or multiple

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methods of use within a single application. Thus, the first appearing composition is combined with a corresponding first method of using and the additional composition and method claims each constitute a separate group.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The peptide sequence having different variables have different and distinct structures. There is no common structure present. For example, an amino acid sequence having PhAc-Phe-Tyr-D-Arg-Asp-Ala-Ile-Phe-Thr-Asn-His-Tyr-His-Tyr-Lys-Val-LeuGly-Leu-Ser-Ala-His-Lys-Leu-Leu-Gln-Asp-Ile-Met-Arg-Arg-Arg-NH<sub>2</sub> is not structurally the same as an amino acid sequence having 1-Nac-Arg-His-D-Cit-Asp-Ala-Val-Tyr-Thr-D-Asn-D-His-Tyr(Me)-D-His-D-Lys-Val-Leu-Ala-Arg-Leu-SerIAbu-D-His-D-Lys-Ala-Leu-Gln-Asp-Ile-Leu-D-Arg-D-Arg-D-Arg-NH-NH<sub>2</sub>. Further, search for one would not necessarily lead to the other.

The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity; and
- (B)
  - (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or
  - (B)
    - (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

In paragraph (B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

4. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

5. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election

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shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

6. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

7. **Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.**

### ***Election***

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Peptide formula: R<sub>1</sub>-A<sup>0</sup>-A<sup>1</sup>-A<sup>2</sup>-Asp-Ala-A<sup>5</sup>-A<sup>6</sup>-Thr-A<sup>8</sup>-A<sup>9</sup>-A<sup>10</sup>-A<sup>11</sup>-A<sup>12</sup>-Val-Leu-A<sup>15</sup>-  
A<sup>16</sup>-Leu-Ser-A<sup>19</sup>-A<sup>20</sup>-A<sup>21</sup>-A<sup>22</sup>-Leu-Gln-Asp-Ile-A<sup>27</sup>-A<sup>28</sup>-A<sup>29</sup>-A<sup>30</sup>-R<sub>2</sub>;

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Variables:  $R_1$ ,  $A^0$ ,  $A^1$ ,  $A^2$ ,  $A^5$ ,  $A^6$ ,  $A^8$ ,  $A^9$ ,  $A^{10}$ ,  $A^{11}$ ,  $A^{12}$ ,  $A^{15}$ ,  $A^{16}$ ,  $A^{19}$ ,  $A^{20}$ ,  $A^{21}$ ,  $A^{22}$ ,  $A^{27}$ ,  $A^{28}$ ,  $A^{29}$ ,  $A^{30}$ , Y and  $R_2$ ;

Peptide Sequence Numbers: 67-82, 86-89, 91-121, 67, 69-70, 72, 76-77, 79-80, 2-19, 21-28, 30-43, 45-60, 62-65, 84-85, 90.

7. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-7.

The following claim(s) are generic: Claims 1-7.

10. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The peptide sequences have different structures due to different amino acids and variables making each peptide sequence independent and distinct. Search for one would not necessarily lead to the other. For example search for PhAc-Phe-Tyr-D-Arg-Asp-Ala-Val-Phe-Thr-Asn-His-Tyr-His-Lys-Val-Leu-Gly-Arg-Leu-Ser-Ala-His-Lys-Leu-Leu-Gln-Asp-Ile-Met-Arg-Cit-Arg-OH would not necessarily lead to Peptide 8, 76 or 100.

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11. The Applicants are requested to elect a single disclosed species for any Group elected. For example, if Group I is elected, then the Applicants are requested to elect a single disclosed species of a peptide with all variables selected from R<sub>1</sub>, A<sup>0</sup>, A<sup>1</sup>, A<sup>2</sup>, A<sup>5</sup>, A<sup>6</sup>, A<sup>8</sup>, A<sup>9</sup>, A<sup>10</sup>, A<sup>11</sup>, A<sup>12</sup>, A<sup>15</sup>, A<sup>16</sup>, A<sup>19</sup>, A<sup>20</sup>, A<sup>21</sup>, A<sup>22</sup>, A<sup>27</sup>, A<sup>28</sup>, A<sup>29</sup>, A<sup>30</sup>, Y and R<sub>2</sub>. For example, as paragraph 9, the peptide elected is PhAc-Phe-Tyr-D-Arg-Asp-Ala-Val-Phe-Thr-Asn-His-Tyr-His-Lys-Val-Leu-Gly-Arg-Leu-Ser-Ala-His-Lys-Leu-Leu-Gln-Asp-Ile-Met-Arg-Cit-Arg-OH from claim 1 for Group I or II.

12. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

13. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

14. **Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.**

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim



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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusions***

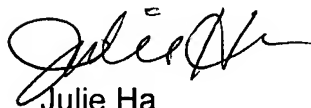
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982.

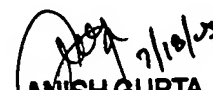
The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Julie Ha  
Patent Examiner  
AU1654

  
ANISH GUPTA  
PRIMARY EXAMINER